

**NATIONAL
MARROW
DONOR
PROGRAM®**

Entrusted to operate the C.W. Bill Young Cell Transplantation Program,
including Be The Match Registry®

January 26, 2012

CDR Sheri Parker
Office of Naval Research (ONR 342)
875 N. Randolph St.
Arlington, VA 22203-1995

Subject: Quarterly Performance/Technical Report of the National Marrow Donor Program®

Reference: Grant Award #N00014-10-1-0204 between the Office of Naval Research and the National Marrow Donor Program

Dear Cdr. Parker:

Enclosed is subject document which provides the performance activity for each statement of work task item of the above reference for the period of October 1, 2011 to December 31, 2011.

Should you have any questions as to the scientific content of the tasks and the performance activity of this progress report, you may contact our Chief Medical Officer – Dennis L Confer, MD directly at 612-362-3425.

With this submittal of the quarterly progress report, the National Marrow Donor Program has satisfied the reporting requirements of the above reference for quarterly documentation. Other such quarterly documentation has been previously submitted under separate cover.

Please direct any questions pertaining to the cooperative agreement to my attention at 612-362-3403 or at cabler@nmdp.org.

Sincerely,



Carla Abler-Erickson, MA
Sr. Contracts Representative

Enclosure: Quarterly Report with SF298

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14. ABSTRACT <u>1. Contingency Preparedness:</u> Collect information from transplant centers, build awareness of the Transplant Center Contingency Planning Committee and educate the transplant community about the critical importance of establishing a nationwide contingency response plan. <u>2. Rapid Identification of Matched Donors :</u> Increase operational efficiencies that accelerate the search process and increase patient access are key to preparedness in a contingency event. <u>3. Immunogenetic Studies:</u> Increase understanding of the immunologic factors important in HSC transplantation. <u>4. Clinical Research in Transplantation:</u> Create a platform that facilitates multicenter collaboration and data management.					
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Grant Award N00014-10-1-0204

DEVELOPMENT OF MEDICAL TECHNOLOGY
FOR CONTINGENCY RESPONSE TO MARROW TOXIC AGENTS
QUARTERLY
PERFORMANCE / TECHNICAL REPORT
FOR
OCTOBER 01, 2011 to DECEMBER 31, 2011
PERIOD 7

Office of Naval Research

And

The National Marrow Donor Program
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QUARTER PROGRESS REPORT**Development of Medical Technology for Contingency Response to Marrow Toxic Agents****April 01, 2011 through June 30, 2011**

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	Task 3 – Expand Immunobiology Research	Open	10
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IIA. Contingency Preparedness – Objective 1: Recovery of casualties with significant myelosuppression following radiation or chemical exposure is optimal when care plans are designed and implemented by transplant physicians

IIA.1 Task 1: Secure Interest of Transplant Physicians

Period 7 Activity:

- No activity during this reporting period

IIA.1 Task 2: GCSF in Radiation Exposure

Period 7 Activity:

- No activity during this reporting period

IIA.1 Task 3: Patient Assessment Guidelines and System Enhancements

Period 7 Activity:

- No activity during this reporting period

IIA 1 Task 4: National Data Collection Model – This task is closed.

IIA. Contingency Preparedness – Objective 2: Coordination of the care of casualties who will require hematopoietic support will be essential in a contingency situation.

IIA.2 Task 1: Contingency Response Network

Period 7 Activity:

- The web based learning management system (LMS) implementation began on November 1 with vendor SumTotal.
- Continued to maintain and test the Iridium satellite telephones issued to RITN centers

IIA.2 Task 2: Sibling Typing Standard Operating Procedures

Period 7 Activity:

- No activity during this reporting period

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IIA. Contingency Preparedness – Objective 3: NMDP's critical information technology infrastructure must remain operational during contingency situations that directly affect the Coordinating Center.

IIA.3 Task 1:
I.S. Disaster Recovery

Period 7 Activity:

- No activity during this reporting period

IIA.3 Task 2:
Critical Facility and
Staff Related
Functions

Period 7 Activity:

- No activity during this reporting period

IIB. Rapid Identification of Matched Donors – Objective 1: Increasing the resolution and quality of the HLA testing of volunteers on the registry will speed donor selection.

IIB.1 Task 1:
Increase Registry
Diversity

Period 7 Activity:

- During this past quarter, as an ongoing project of reviewing rare alleles reported on donors in the Be The Match Registry, 207 donors with rare alleles were identified and retyped at a contract lab for HLA-A, B, or DRB1. To date this project has evaluated the rare allele assignment at HLA-A, B, C, or DRB1 in 1730 samples. In total, 1028 (60%) donor typings have changed from the previously reported rare allele and 702 donor typings have been confirmed to carry the reported rare allele. Additionally, four donors whose typing was corrected have since been requested for confirmatory typing on behalf of a search patient. It is unlikely these donors would have been chosen if their typing had not been corrected.

IIB.1 Task 2: Evaluate HLA-DRB1 High Res typing – This task is closed.

IIB.1 Task 3: Evaluate HLA-C Typing of Donors – This task is closed.

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IIB.1 Task 4: Evaluate Buccal Swabs	Period 7 Activity: Sample Storage Research Study (SSRS) In September, 2011, 30 donor samples (frozen blood, blood spotted onto filter paper, and 2 buccal swabs for each donor) were sent to two laboratories for the 4 year time point of this study. Analysis of the data shows: <ul style="list-style-type: none"> • 100% accuracy in HLA typing at both Intermediate and High Resolution • all sample types contained DNA of sufficient quality and quantity to accurately obtain HLA results at all loci tested (HLA-A, B, C, DRB1, DQB1) • the DNA extracted from the buccal swabs appears to be moderately degraded - 5 samples required the use of the second buccal swab for HLA typing • A 1.2Kb HLA-C amplicon was successfully generated for both the frozen blood samples and blood spotted onto filter paper samples. Amplification of the buccal swab DNA samples was problematic. However, amplicons under 1.0Kb for the HLA testing were successfully amplified from the buccal swab DNA.
IIB 1 Task 5: Enhancing HLA Data for Selected Donors	Period 7 Activity: The AB only donor DRB1 typing project shipped the final DNA samples for testing, AB only donors with repository samples were identified from daily queries of NMDP preliminary patients with zero 6/6 HLA-A/B/DRB1 potential allele matches. Results: <ul style="list-style-type: none"> • By quarter's end a total of 3,762 samples, corresponding to 211 patient searches, had been shipped for DRB1 testing • Only two total DRB1 allele matched donors were identified in the project • One of the DRB1 matches went to transplant in December as a full 10/10 match for the associated patient with no previous 6/6 potentials • The second DRB1 match subsequently mismatched the project patient at both the A and C locus

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	<ul style="list-style-type: none"> The project abstract submitted for consideration was accepted for a poster at the ASBMT 2012 Tandem meeting <p>In addition, a project was initiated to evaluate the benefit of HLA testing DRB1 on 825 minority AB only donors. In this period samples were sent to the lab for testing. This project looks at the underlying genetic diversity of the AB only donors in the Be The Match Registry to determine the usefulness of testing this pool who largely do not have stored DNA samples.</p>
IIB 1 Task 6: Maintain a Quality Control Program – This task is closed.	
IIB. Rapid Identification of Matched Donors – Objective 2: Primary DNA typing data can be used within the registry to improve the quality and resolution of volunteer donor HLA assignments.	
IIB 2 Task 1: Collection of Primary Data	Period 7 Activity: <ul style="list-style-type: none"> No activity during this reporting period
IIB 2 Task 2: Validation of Logic of Primary Data – This task is closed.	
IIB 2 Task 3: Reinterpretation of Primary Data – This task is closed.	
IIB 2 Task 4: Genotype Lists & Matching Algorithm	Period 7 Activity: <ul style="list-style-type: none"> No activity during this reporting period
IIB. Rapid Identification of Matched Donors – Objective 3: Registry data on HLA allele and haplotype frequencies and on the nuances of HLA typing can be used to design computer algorithms to predict the best matched donor.	
IIB.3 Task 1: Phase I of EM Haplotype Logic	Period 7 Activity: <p>We have implemented the third version of the HapLogic algorithm with increased precision and clarity during this reporting period to include:</p> <ul style="list-style-type: none"> 3 locus matching → 5 locus matching x of 6 → x of 8, x of 10 predictions 5 broad race groups → 5 broad and 18 detailed race groups Ensuring visibility of NMDP's best matched donors and cords

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	<ul style="list-style-type: none"> • More precision for mismatch searches • Better aligned with clinical practice
IIB 3 Task 2: Enhancement of EM Algorithm	Period 7 Activity: <ul style="list-style-type: none"> • Completed validation of 6-locus haplotype frequency data in context of new matching algorithm HapLogic III. • HapLogic III released on 2011-12-19 with significant performance enhancements achieved. • First draft of manuscript describing 6-locus haplotype frequency data circulated to co-authors. • DPA1~DPB1 haplotype frequency manuscript submitted to journal Immunogenetics.
IIB 3 Task 3: Optimal Registry Size Analysis	Period 7 Activity: <ul style="list-style-type: none"> • No activity during this reporting period
IIB 3 Task 4: Target Under- Represented Phenotypes	Period 7 Activity: <ul style="list-style-type: none"> • No activity during this reporting period
IIB 3 Task 5: Bioinformatics Web Site – This task is closed.	
IIB 3 Task 6: Consultants to Improve Algorithm – This task is closed.	
IIB 3 Task 7: Population Genetics – This task is closed.	
IIB 3 Task 8: Haplotype Matching – This task is closed.	
IIB 3 Task 9: Global Haplotype/Benchmark – This task is closed.	

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IIB. Rapid Identification of Matched Donors – Objective 4: Reducing the time and effort required to identify closely matched donors for patients in urgent need of HSC transplants will improve access to transplantation and patient survival in the context of a contingency response and routine patient care.

IIB.4 Task 1:
Expand Network
Communications

Period 7 Activity:

- No activity during this reporting period.

IIB.4 Task 2:
Central Contingency
Management

Period 7 Activity:

Donor testing was completed for the research project to validate the “actual” HLA-A, B, C and DRB1 (8/8) high resolution match rates for CAU, AFA, HIS, and API patients. Testing was done on new samples from swab kits sent to donors that had no remaining stored repository samples.

Analysis for 10/10 high resolution matches (adding DQB1) on patients where an 8/8 match was identified continued. In this period approximately 530 donors were typed.

IIB.4 Task 3: Benchmarking Analysis – This task is closed.

IIB.4 Task 4: Expand Capabilities of Collection and Apheresis Centers – This task is closed.

IIC. Immunogenetic Studies – Objective 1: HLA mismatches may differ in their impact on transplant outcome, therefore, it is important to identify and quantify the influence of specific HLA mismatches. In contingency situations it will not be possible to delay transplant until a perfectly matched donor can be found.

IIC.1 Task 1:
Donor Recipient Pair
Project

Period 7 Activity:

- No activity during this reporting period

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IIC. Immunogenetic Studies – Objective 2: Even when patient and donor are HLA matched, GVHD occurs so other loci may play a role.

IIC 2 Task 1:
Analysis of non-HLA loci

Period 7 Activity:

- No activity during this reporting period

IIC 2 Task 2: Related Pairs Research Repository – This task is closed.

IIC 2 Task 3: CIBMTR Integration – This task is closed.

IID. Clinical Research in Transplantation – Objective 1: Clinical research in transplantation improves transplant outcomes and supports preparedness for a contingency response.

IID.1 Task 1:
Observational Research, Clinical Trials and NIH Transplant Center

Period 7 Activity:**Cord Blood Research**

- The Duke and St. Louis Cord Blood Bank (SLCBB) created and finalized training and validating the assay methodologies to ensure the generation of consistent results at both testing sites for the study investigating biomarkers associated with cord blood engraftment.
 - Testing using this third laboratory, SLCBB, is under development to determine whether the poor reliability is due to center-specific or assay related issues.
- Contract negotiations with SLCBB were initiated and finalized.

IID.1 Task 2: Research with NMDP Donors – This task is closed.

IID.1 Task 3:
Expand Immunobiology Research

Period 7 Activity:

The CIBMTR IBWC met monthly during the quarter to discuss progress on ongoing research studies

- Biostatistical analysis continued on ongoing studies.

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AABB	American Association of Blood Banks	HR	High Resolution
AFA	African American	HRSA	Health Resources and Services Administration
AGNIS	A Growable Network Information System	HSC	Hematopoietic Stem Cell
AML	Acute Myelogenous Leukemia	IBWC	Immunobiology Working Committee
ABD	Antigen Binding Domain	IDM	Infectious Disease Markers
API	Asian Pacific Islander	IHWG	International Histocompatibility Working Group
ARS	Acute Radiation Syndrome (also known as Acute Radiation Sickness)	IPR	Immunobiology Project Results
ASBMT	American Society for Blood and Marrow Transplantation	ICRHER	International Consortium for Research on Health Effects of Radiation
ASHI	American Society for Histocompatibility and Immunogenetics	IND	Investigational New Drug
B-LCLs	B-Lymphoblastoid Cell Lines	IS	Information Services
BARDA	Biomedical Advanced Research and Development Authority	IT	Information Technology
BBMT	Biology of Blood and Marrow Transplant	IRB	Institutional Review Board
BCP	Business Continuity Plan	JCAHO	Joint Commission on Accreditation of Healthcare Organizations
BCPeX	Business Continuity Plan Exercise	KIR	Killer Immunoglobulin-like Receptor
BMCC	Bone Marrow Coordinating Center	MDACC	MD Anderson Cancer Center
BMDW	Bone Marrow Donors Worldwide	MDS	Myelodysplastic Syndrome
BMT	Bone Marrow Transplantation	MHC	Major Histocompatibility Complex
BMT CTN	Blood and Marrow Transplant - Clinical Trials Network	MICA	MHC Class I-Like Molecule, Chain A
BODI	Business Objects Data Integrator	MICB	MHC Class I-Like Molecule, Chain B
BRT	Basic Radiation Training	MKE	Milwaukee
C&A	Certification and Accreditation	MRD	Minimal Residual Disease
CAU	Caucasian	MSKCC	Memorial Sloan-Kettering Cancer Center
CBMTG	Canadian Blood and Marrow Transplant Group	MSP	Minneapolis
CBB	Cord Blood Bank	MUD	Matched Unrelated Donor
CBC	Congressional Black Caucus	NAC	Nuclear Accident Committee

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CBS	Canadian Blood Service	NCBM	National Conference of Black Mayors
CBU	Cord Blood Unit	NCI	National Cancer Institute
CHTC	Certified Hematopoietic Transplant Coordinator	NEMO	N-locus Expectation-Maximization using Oligonucleotide typing data
CIBMTR	Center for International Blood & Marrow Transplant Research	NHLBI	National Heart Lung and Blood Institute
CIT	CIBMTR Information Technology	NIH	National Institutes of Health
CLIA	Clinical Laboratory Improvement Amendment	NIMS	National Incident Management System
CME	Continuing Medical Education	NK	Natural Killer
CMF	Community Matching Funds	NLE	National Level Exercise
COG	Children's Oncology Group	NMDP	National Marrow Donor Program
CREG	Cross Reactive Groups	NRP	National Response Plan
CSS	Center Support Services	NST	Non-myeloablative Allogeneic Stem Cell Transplantation
CT	Confirmatory Testing	OCR/ICR	Optical Character Recognition/Intelligent Character Recognition
CTA	Clinical Trial Application	OIT	Office of Information Technology
DC	Donor Center	OMB	Office of Management and Budget
DHHS-ASPR	Department of Health and Human Service – Assistant Secretary Preparedness and Response	ONR	Office of Naval Research
DIY	Do it yourself	P2P	Peer-to-Peer
DKMS	Deutsche Knochenmarkspenderdatei	PBMC	Peripheral Blood Mononuclear Cells
DMSO	Dimethylsulphoxide	PBSC	Peripheral Blood Stem Cell
DoD	Department of Defense	PCR	Polymerase Chain Reaction
DHHS-ASPR	Department of Health and Human Services – Assistant Secretary for Preparedness and Response	PSA	Public Service Announcement
DNA	Deoxyribonucleic Acid	QC	Quality control
DR	Disaster Recovery	RCC	Renal Cell Carcinoma
D/R	Donor/Recipient	RCI BMT	Resource for Clinical Investigations in Blood and Marrow Transplantation
EBMT	European Group for Blood and Marrow	REAC/TS	Radiation Emergency Assistance Center/Training Site

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	Transplantation		
EDC	Electronic Data Capture	RFP	Request for Proposal
EFI	European Federation of Immunogenetics	RFQ	Request for Quotation
EM	Expectation Maximization	RG	Recruitment Group
EMDIS	European Marrow Donor Information System	RITN	Radiation Injury Treatment Network
ENS	Emergency Notification System	SBT	Sequence Based Typing
ERSI	Environment Remote Sensing Institute	SCTOD	Stem Cell Therapeutics Outcome Database
FBI	Federal Bureau of Investigation	SG	Sample Group
FDA	Food and Drug Administration	SLCBB	St. Louis Cord Blood Bank
FDR	Fund Drive Request	SLW	STAR Link® Web
FLOCK	Flow Cytometry Analysis Component	SSA	Search Strategy Advice
Fst	Fixation Index	SSO	Sequence Specific Oligonucleotides
GETS	Government Emergency Telecommunications Service	SSP	Sequence Specific Primers
GCSF	Granulocyte-Colony Stimulating Factor (also known as filgrastim)	SSOP	Sequence Specific Oligonucleotide Probes
GIS	Geographic Information System	SSRS	Sample Storage Research Study
GvHD	Graft vs Host Disease	STAR®	Search, Tracking and Registry
HCS	HealthCare Standard	TC	Transplant Center
HCT	Hematopoietic Cell Transplantation	TED	Transplant Essential Data
HEPP	Hospital Emergency Preparedness Program	TNC	Total Nucleated Cell
HHQ	Health History Questionnaire	TSA	Transportation Security Agency
HHS	Health and Human Services	UI	User Interface
HIPAA	Health Insurance Portability and Accountability Act	UML	Unified Modeling Language
HIS	Hispanic	URD	Unrelated Donor
HLA	Human Leukocyte Antigen	WGA	Whole Genome Amplification
HML	Histoimmunogenetics Mark-up Language	WMDA	World Marrow Donor Association
		WU	Work-up